

Deputy Director, NHLI

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Special Assistant for Technology
NHLI

Input on technology for the updated National Plan

The attached is submitted after conferring with Dr. Cooper upon the propriety of input by other than a Director. He has not reviewed the content.

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NHLI:CDennis:mmh

Stringency of funds and personnel led to dissolution of DTA early in FY 1974. One result was the transfer of the former director of that Division into the OD/NHLI as Special Assistant for Technology. In the course of gathering material for a position paper and with the perspective secondary to freedom from involvement in the minutiae of the program, certain observations have been made concerning the work under contract on development of the artificial heart.

Certain decisions were made at the time of embarkation upon the program of the artificial heart. An ad hoc Advisory Group worked through most of 1966, and among the conclusions were the following*:

"The contractor's report also discussed some of the ways in which a program to develop an artificial heart might be administered so as to capitalize upon the strengths inherent in the scientific research community and at the same time draw upon the resources of the industrial engineering community. One possibility, to turn the entire direction over to a large industrial contractor, was ruled out because it would tend to destroy the open cooperation and communication characteristic of this group entirely. The opposite alternative, to have the development carried out by basic researchers in academic, medical and engineering institutions, was also ruled out because these groups were ill-equipped to build the things that would be needed for the development of the devices and it would be diverting their time and energies from the more basic problems for which their contributions were so valuable.

"Rejecting these extremes, the other alternatives were to establish an organizational structure that would provide direction and coordination for the program, drawing upon the resources of industry, medicine, basic science and engineering, systems management, etc., as appropriate to a particular facet of the overall development. This organization could be established as an outside organization combining these various resources or could reside in NIH. Implicit in both of these alternatives was the desire to establish and retain effective working relationship among the various groups.

"During discussion of these issues, the advisory group agreed that it was desirable to have the coordinating function reside in NIH."

While this was a sound decision to make under the conditions which existed at that time, the conditions of the past few months dictate reconsideration. The work of the program has become increasingly complex, coordination has become increasingly essential, manpower in NIH for this purpose has become inadequate to the job, and the where-withal to attract scientific monitors with the essential expertise has not been made available.

*The Artificial Heart Program: An Historical Overview. Robert L. Ringler, Feb. 1969. Prepared for presentation to the NHL ad hoc Committee on Cardiac Replacement.

Effective performance of the program in this area is dependent upon coordinated performance of a group of contractors. Such coordination has been and still is seriously undermined by the combination of two factors. These are:

1. Lack of success in finding contractors in key areas willing and able to mount scientific endeavors on a high plane. (They therefore can be fruitful in the program only if given intensive monitoring and guidance from NHLI); and
2. Lack of the necessary expertise in depth in NHLI to provide such monitoring and guidance. This is due to two factors:
 - a. An absolute inadequacy of numbers of personnel, and
 - b. An inadequacy of representation of the necessary breadth of expertise required to provide such monitoring and guidance.

Inasmuch as the factors above render it unlikely that a well-coordinated program can be mounted by staff within NHLI, it is proposed that a prime non-profitmaking contractor be chosen or established anew with selection of personnel by meticulous screening by NHLI for the purpose of:-

1. Administration of a specialized center of research or research and demonstration center in the artificial heart and related instrumentation (or for technological development for NHLI);
2. Performance on site of confirmatory and exploratory laboratory work as indicated for each step in the course of work of contractors; and
3. Coordination of all the work in the program with a computerized retrieval pattern of systems analysis.

Such a center must be adjacent to a vigorously active clinical program in cardiovascular medicine and surgery. This could be a portion of the SCOR or Research and Demonstration Center in which case further funding would be required than that listed here.

The funding proposed:*

FY	75	76	77	78	79	80
	3500K	3000K	2000K	2200K	2300K	2000K

*These figures are for the operation of this contractor alone. Funds for issuance of subcontracts should be achieved by transfer from the contracts formerly in DTA. The initial years are higher because of anticipated reconstruction.

The advantages of this proposal are:

1. It facilitates the setting up of a pattern of specialized systems management, including use of computerized storage of information so badly needed in a highly technical multifaceted program. The present program suffers for lack of such management.
2. It permits recruitment of the top brains in each of specialized areas involved through both provision of adequate salaries and provision of an opportunity to continue with that central laboratory work essential to the program.
3. It provides a structure with the ability to drop those staff members who prove disappointing, one of the problems in the present NHLI pattern.
4. It provides a center with a laboratory in which confirmation of the work of subcontractors can be done at each step along the way and a central laboratory in which some aspects of the work of the program can better be performed than in the establishments of the subcontractors.



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